

Applicants: Alberto Martin, et al.  
Application No.: 10/501,628  
Filed: November 22, 2004

### **REMARKS**

Claims 1-9, 13, 15, 18-25, 58, 97, 125, and 262-307 are pending in the subject application.

#### **New Examiner**

Applicants acknowledge that the present application has been transferred to new Examiner Michael D. Burkhart.

#### **Election of Species Requirement**

The Examiner is requiring, based on the amended claims and submission of claims 301-307, further restriction of the claims based on the type of cell to be used in the methods of the invention. Specifically, the Examiner is requiring an election from the cell types recited in claims 21 (a B cell), 22 (a hybridoma), 97 (a myeloma), 304 (a non-B cell), 305 (a non-B cell), 306 (a non-B cell) and 307 (a hybridoma).

The Examiner states at page 3 of the Office Action that:

The species listed above do not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the cell types recited in claims 21, 22, 97 and 304-307 are mutually exclusive, and thus each has a different special technical feature from the others. For example, a comparison of claim 21 with claims 304-306 reveals that the cells recited in the claims are mutually exclusive of one another, i.e., a B cell would not read on a non-B cell and visa versa. The same is true for a comparison of claim 97 and claim 304, a myeloma would not read on a hybridoma, and vice versa. [Emphasis added.]

Applicants respectfully disagree and elect non-B cells with traverse. Claims 1-9, 13, 15, 18, 19, 20, 23-25, 58, 125 and 262-306 read on the elected species.

The traversal is on the following grounds:

The present application is a national stage §371 application. Pursuant to MPEP 1893.03(d) and PCT Rule 13.2, “[a] group of inventions is considered linked to form a single

general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, as a whole, makes over the prior art." [Emphasis added.]

The pending claims are directed to methods of inducing and identifying a mutation in a gene of interest; or an antibody gene; as a system for changing the affinity or specificity of an antibody; or for inducing class switch recombination in an antibody gene, as exemplified by independent claims 1, 58, 97 and 125.

Applicants note that **all these claimed methods** rely in part, upon the step of expressing a transgenic AID gene in a cell, and upon the Applicants' discovery that such transgenic AID expression is solely sufficient to induce somatic hypermutation in a gene of interest in a eukaryotic cell (see independent claims 1, 58, 97 and 125). The transgenic AID expression is independent of the cell type in which it takes place. Thus, the special technical feature of the claims is found in the independent claims in the recitation of expression of a transgenic AID gene in the cell and expressing the gene subject to mutation in the cell. See also, arguments made of record. As such, the claimed methods are independent of the cell type in which AID expression takes place; Applicants assert, therefore, that a restriction among the cell types is improper and that the Examiner has failed to establish a *prima facie* case that the cell types do not share a single inventive concept of the invention, as a whole, in accordance with Unity of Invention as set forth in MPEP § 1893.03(d).

Secondly, Applicants note that the Examiner is incorrect in asserting that the disclosed cell types represent mutually exclusive species. Specifically for example, Applicants respectfully note that that hybridomas are immortalized B cells that can be formed by fusion of **either** B or T lymphocytes with non secreting B cell Myeloma cells, and are capable of infinite division (see for example, Office Action dated 09/13/2007, page 2). Therefore, depending on the nature of how the hybridoma cells recited in claims 22 and 307 were formed, they could represent either a B-cell or a non B cell, or even be considered to be a form of myeloma (as recited in claim 97). Thus, the claims overlap in scope and share a special technical feature; and, therefore, in contrast to the Examiner's assertions, are not mutually exclusive. Applicants'

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statements are not to be taken as an admission that the types of cells are obvious in view of each other.

PCT Rule 13.4 states:

Subject to Rule 13.1, it shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any independent claim could be considered as constituting in themselves an invention.

In addition, Applicants note that claims 1, 58, 97 and 125 are generic claims linking elected and non-elected species. Claims 21, 22, 97 and 304-307 are dependent claims of claims 1, 58, 97 and 125 including all limitations of the generic claims.

Pursuant to MPEP § 809.03, “[i]f a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the non-elected inventions that are linked to the elected invention by such allowed linking claim.” Thus, restrictions imposed on species encompassed by generic claims must be withdrawn upon indication of an allowable generic claim (MPEP § 809). In other words, upon the allowance of a generic claim, Applicants are entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141 (MPEP § 809.02(a)). The burden is on the Examiner to examine these generic claims throughout their scope, together with any claims dependent thereon drawn to non-elected species or inventions, rather than for Applicants to limit the scope of the generic claims to conform to the scope of any species or inventions listed in a species election.

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### CONCLUSIONS

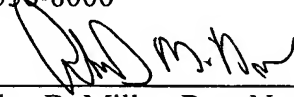
In view of the above remarks, reconsideration of the species election, and allowance of the application are respectfully requested. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned attorney.

No fee is deemed necessary in connection with the filing of this reply. However, if any fee is required to maintain the pendency of the subject application, authorization is hereby given to withdraw the amount of any such fee from Deposit Account No. 01-1785.

Respectfully submitted,

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By   
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